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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,016	03/23/2004	David Feygin	115-004US	4798

22897 7590 10/06/2008

DEMONT & BREYER, LLC
100 COMMONS WAY, Ste. 250
HOLMDEL, NJ 07733

EXAMINER	
FRISBY, KESHA	
ART UNIT	PAPER NUMBER
3715	
MAIL DATE	DELIVERY MODE
10/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,016	FEYGIN ET AL.	
	Examiner	Art Unit	
	KESHA FRISBY	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,13-19,21-25,28 and 33-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-7, 13-19, 21-25, 28 & 33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

After the amendment was filed on 7/8/2008, claims 1, 4-7, 13-19, 21-25, 28 & 33-40 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement filed 12/4/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the Foreign Patent Document does not include a translation. The examiner is unable to determine what the document entails since it is in a foreign language. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 & 2 currently recites "... a first device/second device for performing a first/second skin-interaction technique that is

used in conjunction with a simulated vascular-access procedure, wherein the first/second skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein:

(a) said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin …, Claim 25 currently recites "… a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin, and wherein said plurality of mechanisms include:

(a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin …" and claim 35 currently recites a plurality of mechanisms with which a user interacts for simulating a vascular- access procedure, including at least one mechanism for performing a non-invasive skin interaction technique that is performed on said pseudo skin, wherein said plurality of mechanisms are disposed under said pseudo skin and are covered by said pseudo skin ..". The examiner is unsure as to how the first device/first mechanism/plurality of mechanism is first used for performing a first skin-interaction technique that is performed on the skin but the first device is disposed beneath the skin.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 1, 35 & 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (U.S. Patent Number 6,654,000) in view of Pugh (U.S. Publication Number 2003/0031993).

Referring to claim 1, Rosenberg discloses pseudo skin (barrier 22); a receiver (trocar 24), wherein said receiver receives an end effector (laparoscopic tool 18) through an insertion region in said pseudo skin (column 5 lines 38-47); and a first device (mechanical apparatus 25) for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin (Fig. 1 & column 5 lines 37-56). *Rosenberg does not explicitly disclose a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin and further said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.* However, Pugh teaches a first device (sensors) for performing a first skin-interaction technique (paragraph 0012) that is used in conjunction with a simulated vascular-access procedure (paragraph 0062), wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction

region of the pseudo skin (Fig. 3 and paragraphs 0041 & 0042) and further said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus (One region would be closer to a user then another region, depending on the location of the user with respect to the apparatus and paragraph 0044 and it is well known in the art the to tie off the vein or palpate the vein above the insertion point). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include palpation, as disclosed by Pugh, incorporated into Rosenberg in order to check for organs that on the organ surface or on the skin.

Referring to claim 35, Rosenberg discloses a pseudo skin (barrier 22); a plurality of mechanisms with which a user interacts for simulating a vascular- access procedure (mechanical apparatus 25 and trocar 24), wherein said plurality of mechanisms are disposed under said skin and are covered by said pseudo skin (column 5 lines 37-56); and a housing (within the "body" of the patient), wherein said housing contains said plurality of mechanisms (Fig. 1 & column 5 lines 37-56). *Rosenberg does not explicitly disclose including at least one mechanism for performing a non-invasive skin-interaction technique that is performed on said pseudo skin.* However, Pugh teaches including at least one mechanism (paragraph 0012) for performing a skin-interaction technique that is performed on said pseudo skin (paragraph 0062). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include palpation, as disclosed by Pugh, incorporated into Rosenberg in order to check for organs that on the organ surface or on the skin.

Referring to claim 38, Rosenberg discloses wherein at least one of either a needle or catheter is disposed outside of said housing until inserted therein during a simulated vascular-access procedure (Fig. 1 & the associated text).

Referring to claim 39, Rosenberg discloses further comprising a data processing system, wherein said data processing system receives signals from sensors that are associated with said plurality of mechanisms (column 10 lines 22-24).

Referring to claim 40, Rosenberg discloses wherein said plurality of mechanisms comprise discrete devices, wherein a first of said devices (column 11 line 47- column 12 line 2) is for enabling a user to perform a skin-stretch technique, a second of said devices (trocar 24) is for receiving a needle or catheter or both, and a third of said devices (column 12 lines 46-49) is for enabling a user to perform at least one of either a palpation technique or an occlusion technique.

6. Claims 4-7 & 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg/Pugh and further in view of Cunningham et al. (U.S. Patent Number 6,470,302).

Referring to claims 4 & 5, Rosenberg/Pugh discloses the apparatus of claim 1. *Rosenberg/Pugh does not disclose further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin (claim 4) and wherein: said second skin-interaction technique comprises skin stretching, and said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin*

when said user is using said apparatus (claim 5). However, Cunningham et al. teaches further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin (column 11 lines 32-54), wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin (Figs. 1-7 & the associated text) (claim 4) and wherein: said second skin-interaction technique comprises skin stretching, (column 11 lines 32-54) and said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin when said user is using said apparatus (One region would be closer to a user then another region, depending on the location of the user with respect to the apparatus and Figs. 1-7 & the associated text) (claim 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a second device, as disclosed by Cunningham, incorporated into Rosenberg/Pugh in order to stretch the skin in order to locate the vein.

Referring to claim 6, Rosenberg/Pugh discloses the apparatus of claim 1 and (a) said receiver and said first device are contained within said housing (within barrier 22) and (b) said pseudo skin is substantially co-extensive with a surface of said housing (the same thing so they must be). *Rosenberg/Pugh does not disclose wherein said housing has an anterior portion, a posterior portion, an upper surface and a lower surface wherein, in use: said anterior portion is proximal to a user; said posterior portion is distal to said user; said lower surface is proximal to a support surface on which said apparatus resides; and said upper surface is distal to said support surface.* However, Cunningham et al. teaches said housing has an anterior portion and a posterior portion

(Fig. 3); in use, said anterior portion is proximal to a user; and said posterior portion is distal to said user (Fig. 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include housing, as disclosed by Cunningham et al., incorporated into Rosenberg/Pugh in order to protect the receiver and first device from getting damaged.

Referring to claim 7, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein the upper surface is no more than about 5 inches above the lower surface, the housing units 33 and 40 in Fig. 4 appear to have only a slightly bigger height than the mouse 44. Since a mouse is generally about 1.5 inches high, one could assume that housings 33 and 40 in Fig. 4 are probably about 2 or 3 inches high. Additionally, Pugh discloses that the size of the anatomical simulator and organs represent expected ranges of human size, shape, and other qualities (Paragraph [0038]). Therefore, if the invention were being used to simulate the anatomy of a baby or small child, the height of the anatomical simulator would be less than about 5 inches.

Referring to claim 13, Rosenberg/Pugh, as modified by Cunningham et al., discloses further comprising a second device (paragraph 0012 of Pugh) for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin (paragraphs 0012 & 0013 of Pugh).

Referring to claim 14, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein: said second skin-interaction technique comprises skin stretch (Figs. 14C, 15 & 16 of Pugh).

Referring to claim 15, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein at least some portion of said second device is closer to said anterior portion of said housing than said first device (paragraph 0012 of Pugh).

Referring to claim 16, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein at least some portion of said second device is closer to said anterior portion of said housing than said first end of said receiver (Items 16 & 20 in Fig. 1, paragraph 0037, items 26, 28, 29 & 30 in Fig. 3 & paragraphs 0041 & 0042 of Pugh).

Referring to claim 17, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said first end of said receiver is closer to said anterior portion of said housing than said first device (Fig. 4).

Referring to claim 18, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein an upper-most surface of said first device extends a greater distance above a lowermost surface of said housing than said first end of said receiver (Fig. 2 of Pugh).

Referring to claim 19, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein an upper-most surface of said first device extends further above a lowermost surface of said housing than an upper-most surface of said second device (Fig. 8 of Pugh).

Referring to claim 21, Rosenberg/Pugh, as modified by Cunningham et al., discloses further comprising an electronics/communications interface, wherein: said electronics/communications interface receives signals from sensors that are associated with at least one of said first device or said receiver (paragraphs 0014-0017 of Pugh); and said electronics/communications interface is disposed beneath said pseudo skin

and covered by said pseudo skin (wires located inside simulator of Pugh).

Referring to claim 22, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface is closer to said posterior portion of said housing than said first device (depends on the location of the of the simulated organs or sensors with respect to the wires of Pugh).

Referring to claim 23, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface is closer to said posterior portion of said housing than said receiver (depends on the location of the of the simulated organs or sensors with respect to the wires of Pugh).

Referring to claim 24, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface comprises a printed circuit board, and further wherein a major surface of said printed circuit board is disposed orthogonal to an uppermost surface of said first device (paragraph 0045 & Item 33 in Fig. 4 of Pugh).

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. in view of Rosenberg.

Referring to claim 25, Cunningham et al. discloses housing (30), wherein said housing has an opening in an uppermost surface thereof (Fig. 3); pseudo skin, wherein said pseudo skin covers said opening (column 11 lines 32-54 & Fig. 3); wherein said end effector is inserted into said housing through said pseudo skin during the performance of a simulated vascular-access procedure (virtual needle above a vein & column 11 lines 55-67); and a plurality of mechanisms (components with in 30), wherein said

plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin (components within 30), wherein a first mechanism is for simulating skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin (belt). Cunningham et al does not disclose a second mechanism for receiving said end effector. However, Rosenberg teaches a second mechanism (25) for receiving said end effector (18). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include second mechanism, as disclosed by Rosenberg, incorporated into Cunningham et al. in order to perform the vascular-access procedure.

8. Claims 28 & 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al./Rosenberg and further in view of Pugh.

Referring to claim 28, Cunningham et al./Rosenberg discloses the apparatus of claim 25 and wherein said end effector is at least one of either a needle or a catheter (needles and/or catheters). Cunningham et al./Rosenberg does not disclose wherein said mechanisms includes a third mechanism (column 11 line 47 – column 12 line 2) for simulating at least one of a palpation or an occlusion technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin, and wherein said end effector is at least one of either a needle or a catheter (column 6 lines 4-13). However, Pugh teaches wherein said mechanisms includes a third mechanism (sensor) for simulating at least one of a palpation or an occlusion technique (paragraph 0012) that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin (paragraph 0062). It

would have been obvious to one of ordinary skill in the art at the time the invention was made to include a third mechanism, as disclosed by Pugh, incorporated into Cunningham et al./Rosenberg in order to perform surgical procedures.

Referring to claim 33, Cunningham et al./Rosenberg, as modified by Pugh, teaches wherein said housing has an anterior end and a posterior end (Fig. 3 of Cunningham et al.), wherein in use, said anterior end is proximal to a user; and wherein a portion of said second mechanism is flanked by said first mechanism proximal to said anterior end and said third mechanism proximal to said posterior end (Fig. 3 of Cunningham et al.).

9. **Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al./Rosenberg and further in view of Pugh.**

Referring to claim 34, Rosenberg/Cunningham et al. discloses the apparatus of claim 28 and a user interacts with said first mechanism at a first site on said pseudo skin (column 7 lines 32-54 of Cunningham et al. and said user interacts with said second mechanism (25) at a second site on said pseudo skin (punchers skin). *Cunningham et al./Rosenberg does not disclose wherein the user interacts with the third mechanism at a third site on said pseudo skin.* However, Pugh teaches and wherein the user interacts with the third mechanism at a third site on said pseudo skin (sensors, paragraphs 0012 & 0062); and locations of each of said first site, second site, and third site on said pseudo skin corresponds to locations of said first mechanism, second mechanism, and third mechanism, respectively within said housing, Pugh discloses that a user may interact with a plurality of simulated organs (i.e., mechanisms) via a plurality of openings on the simulator (Figs. 14A-C, 15, and 16). It would have been obvious to one of

ordinary skill in the art at the time the invention was made to include user interaction, as disclosed by Pugh, incorporated in to Cunningham et al./Rosenberg in order to perform medical exams with direct manual contact with a body or organ surface.

10. Claims 36 & 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg.

Referring to claims 36 & 37, Rosenberg et al. discloses the apparatus of claim 35.

Rosenberg does not disclose expressly that the housing is no more than about 4 or 5 inches in height. Instead, Rosenberg indicates using a housing (column 5 lines 54-56).

At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to have the housing having any measurements because Applicant has not disclosed that having adaptive architecture on a second computer provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Rosenberg's system, and applicant's invention, to perform equally well with the housing taught by Rosenberg or the claimed housing is no more than about 4 or 5 inches in height because both housings would perform the same function of contain the mechanism.

Therefore, it would have been prima facie obvious to modify Rosenberg to obtain the invention as specified in claims 36 & 37 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Rosenberg.

Response to Arguments

11. Applicant's arguments filed 7/8/2008 have been fully considered but they are not persuasive. On pages 10 & 11, in regards to claim 1, the applicant argues that claim 1 recites a limitation of "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure." This is rather a specific limitation that narrows the "first skin-interaction technique" to palpating for a vein, occluding a vein, or stretching the skin. A practitioner does NOT palpate an organ "in conjunction with" a simulated vascular-access procedure. The recited "first device" must be a device that enables a user to practice palpating a vein, occluding a vein, or stretching the skin. The examiner would have to disagree with the applicant's assertion. Further clarification above has been made to teach the claimed limitation. Further, the applicant states that a practitioner does NOT palpate an organ "in conjunction with" a simulated vascular-access procedure. The applicant's assertion is untrue. The skin is an organ (biggest organ) and must be palpated in order to locate a patient's vein. The applicant also argues that claim 1 recites a limitation that the "insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus." The examiner has also made further clarification in the above rejection to show that this limitation is taught.

In regards to claims 36 & 37, the examiner had previously stated these measurements as pure design choice. The applicant has argued several points to clarify that these measurements are not intended to be considered as design choice measurements. Although, the applicant has stated some reasons for these measurements, theses

reasons are not specified in the originally filed specification which is a requirement to overcome a design choice rejection. Therefore, these limitations are still being considered a design choice limitation by the examiner.

12. Applicant's arguments with respect to claims 4-6, 25, 28, 33-35 & 38-40 have been considered but are moot in view of the new ground(s) of rejection.

Note: Since claims 13-24 are ultimately dependent upon claim 1 the above rejections, remarks and rationale applies.

Citation of Pertinent Prior Art

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Toly (U.S. Publication Number 2004/0126746) teaches a medical physiological simulator including a conductive elastomer layer.

Hoballah (U.S. Patent Number 6,398,557) teaches devices, methods and kits for training in surgical techniques.

Green (U.S. Patent Number 6,223,100) teaches an apparatus and method for performing computer enhanced surgery with articulated instrument.

Lambroz (U.S. Publication Number 2003/0144691) teaches an inflatable tourniquet.

Eggert (U.S. Publication Number 2003/0073060) teaches an interactive education system for teaching patient care.

Eggert (U.S. Publication Number 2004/0157199) teaches an interactive education system for teaching patient care.

Alexander (U.S. Patent Number 6,929,481) teaches an interactive device and method for interfacing instruments to medical procedure simulation systems.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KESHA FRISBY whose telephone number is (571)272-8774. The examiner can normally be reached on Monday-Friday 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3714

/K. F./
Examiner, Art Unit 3714